



# LFW  
Docket No. TIP0016US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Hendrika et al.

Serial No. : 10/518,525

Art Unit: 1613

Filed : December 22, 2004

Examiner: Whaley, P.

For : NEW MUTATIONAL PROFILES IN HIV-1 REVERSE  
TRANSCRIPTASE CORRELATED WITH PHENOYPIC DRUG  
RESISTANCE

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Yunling Ren

(Name of applicant, assignee, or Registered Representative)

\Yunling Ren\

(Signature)

June 27, 2006

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

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information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☒ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/TIP0016US/YR. This form is submitted in triplicate.

Respectfully submitted,

\Yunling Ren\

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DATED: June 27, 2006



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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	10/518,525
Filing Date	12/22/2004
First Named Inventor	Hendrika
Group Art Unit	1613
Examiner Name	Whaley, P.
Attorney Docket Number	TIP0016US

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Kind Code <sup>2</sup> (if known)	Number			
			327,742	Uren	10/06/1885	

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		EP	406985	A2	Janssen Pharmaceutica,N.V.	01/09/1991		
		EP	428000	A1	Abbott Laboratories	05/22/1991		
		WO	97/27319	A1	Virologic, Inc.	07/31/1997		
		PCT	97/27332	A1	Innogenetics,N.V.	07/31/1997		
		PCT	97/27480	A1	Virco,N.V.	07/31/1997		
		PCT	99/67428	A2	Innogenetics N.V.	12/29/1999		
		PCT	00/73511	A1	Virco NV	12/07/2000		
		PCT	00/78994	A1	The Penn State Research Foundation	12/28/2000		
		PCT	00/78996	A1	Virologic, Inc.	12/28/2000		
		WO	01/79540	A2	Virco, N.V.	10/25/2001		
		PCT	01/81624	A1	Virco N.V.	11/01/2001		
		PCT	01/95230	A2	Virco UK Limited	12/13/2001		
		PCT	02/083657	A2	Tibotec Pharmaceuticals Ltd.	10/24/20002		
		PCT	02/22076	A2	Virologic, Inc.	03/21/2002		
		PCT	02/33402	A2	Virco N.V.	04/25/2002		
		PCT	02/38792	A2	Biolliance Pharma	05/16/2002		
		PCT	04/022523	A2	Elan Pharmaceuticals, Inc.	03/18/2004		
Examiner Signature					Date Considered			

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 3

<b>Application Number</b>	10/518,525
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<b>First Named Inventor</b>	Hendrika
<b>Group Art Unit</b>	1613
<b>Examiner Name</b>	Whaley, P.
<b>Attorney Docket Number</b>	TIP0016US

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		<b>ABSTRACT: International Congress on Drug Therapy in HIV Infection, Volume 12, Supplement 4, AIDS.online.com</b>	
		<b>ABSTRACT: Comprehensive HIV Drug Resistance Monitoring Using Rapid, High-Throughput Phenotypic and Geotypic Assays with Correlative Data Analysis. Poster Abstracts, OP3.4</b>	
		<b>Condra, Jon ., et al. Genetic Correlates of InVivo Viral Resistance to Idvavir, a Human Immunodeficiency Virus Thpe 1 Protease Inhibitor. Journal of Virology, December 1996, pp. 8270-8276</b>	
		<b>GUIDANCE FOR INDUSTRY. U.S. Department of Health and Human Services, Food and Drug Administration</b>	
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		<b>Eriksson, Bertil F.H., et al. Phosphorylation of 3'-Azido-2',3'-Dideoxyuridine and Preferential Inhibition of Human and Simian Immunodeficiency Virus Reverse Transcriptases by Its 5'-Triphosphate. Antimicrobial Agents ad Chemotherapy, Oct 1989, pp. 1729-1734</b>	
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		<b>Harada, Shinji, et al. Infection of HTLV-III/LAV in HTLV-I-Carring Cells MT-2 and MT-4 and Application in a Plaque Assay. Department o Virology and Prasitology, Yamaguchi University, Japan, august 9, 1985, p. 563-566</b>	
		<b>Hertogs, Kurt, et al. A Rapid Method for Simultaneous Detection of Pheotypic Resistance to Inhibitors of Protease and Reverse Transcriptase in Recombinant Human Immunodeficiency Virus Type 1 Isolates from Patients Treated with Antiretroviral Drugs. Antimicrobial Agents ad Chemotherapy, February 1998, pp. 269-276</b>	
		<b>Ibanex, Angela, et al. Human Immunodeficiency Virus Type 1 Population Bottleneck During Indinavir Theraphy Causes a Genetic Drift in the env quasiespecies.. Journal of General Virology, 2000, p. 85-95</b>	
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		<b>Larder, Brendan A., et al. Zidovudine Resistance Predicted by Direct Detection of Mutations in DNA from HIV-infected Lymphocytes. AIDS, 1991, 5:137-144</b>	
		<b>Larder, Brendan A., et al. HIV with a Reduced Sensitivity to Zidovudine (AZT) Isolated During Prolonged Therapy. Reports, March 31, 1980, pp. 1731-1734</b>	
		<b>Lennerstrand, J., et al. A Method for Combined Immunoaffinity Purification and Assay of HIV-1 Reverse Transcriptase Activity Useful for Crude Samples. Analytical Biochemistry 235, 1996, pp.141-152</b>	

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Filing Date	12/22/2004
First Named Inventor	Hendrika
Group Art Unit	1613
Examiner Name	Whaley, P.
Attorney Docket Number	TIP0016US

		Matayoshi, Edmund D., et al. <b>Novel Fluorogenic Substrates for Assaying Retroviral Proteases by Resonance Energy Transfer.</b> Science, Vol. 247, pp. 954-958	
		Miller, Veronica, et al. <b>Patterns of Resistance and Cross-Resistance to Human Immunodeficiency Virus type 1 Reverse Transcriptase Inhibitors in Patients Treated with the Nucleoside Reverse Transcriptase Inhibitor Zalcitabine.</b> Antimicrobial Agents and Chemotherapy, December 1998, pp. 3123-3129	
		Rusconi, Stefano, et al. <b>Susceptibility to PNU-140690 (Tipranavir) of Human Immunodeficiency Virus Type 1 Isolates Derived from Patients with Multidrug Resistance to Other Protease Inhibitors.</b> Antimicrobial Agents and Chemotherapy, May 2000, pp. 1328-1332	
		Stuyver, Lieven, et al. <b>Line Probe Assay for Rapid Detection of Drug-Selected Mutations in the Human Immunodeficiency Virus Type 1 Reverse Transcriptase Gene.</b> Antimicrobial Agents and Chemotherapy, Feb. 1997, pp. 284-291	
		Toth, Mihaly V., et al. <b>A Simple, Continuous Fluorometric Assay for HIV Protease.</b> Int. J. Peptide Protein Res. 36, 1990, pp. 544-550	
		Tyagi, Suresh C., et al. <b>Continuous Assay of the Hydrolytic Activity of Human Immunodeficiency Virus-1 Protease.</b> Analytical Biochemistry 200, pp. 143-145 (1992)	
		Tyagi, Sanjay, et al. <b>Multicolor Molecular Beacons for Allele Discrimination.</b> Nature Biotechnology, January 1998, Volume 16, pp. 49-53	
		Vasudevachari, M.B., et al. <b>Emergence of Protease Inhibitor Resistance Mutations in Human Immunodeficiency Virus Type 1 Isolates from Patients and Rapid Screening Procedure for Their Detection.</b> Antimicrobial Agents and Chemotherapy, November 1996, pp. 2535-2541, Vol. 40, No. 11	
		Vergne, Lurence, et al. <b>Genetic Diversity of Protease and Reverse Transcriptase Sequences in Non-Subtype-B Human Immunodeficiency Virus Type 1 Strains: Evidence of Many Minor Drug Resistance Mutations in Treatment-Naïve Patients.</b> Journal of Clinical Microbiology, November 2000, p. 3919-3925, Vol. 38, No. 11	
		Wang, Gary T., et al. <b>Design and Synthesis of New Fluorogenic HIV Protease Substrates Based on Resonance Energy Transfer.</b> Tetrahedron Letters, Vol. 31, No. 45, pp. 6496-6496	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

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SUBMISSION UNDER MPEP 609 D

Page 1 of 1

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Examiner Name	Whaley, P.
Attorney Docket Number	TIP 0016US

**U.S. PATENT DOCUMENTS**

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**FOREIGN PATENT DOCUMENTS**

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			Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		PCT Search Report dated January 4, 2005, International Application No. PCT/EP 03/50280	
		PCT Search Report dated November 10, 2003, International Application No. PCT/EP 03/50277	
		Patent Application USSN 10/519,035 filed December 22, 2004 ((Docket No. TIP 0014 US)	
		Patent Application USSN 10/519,436 filed December 22, 2004 (Docket No. TIP-0015 US)	

Examiner Signature		Date Considered	
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